PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing *(day/month/year)*	07.07.2004
Applicant's or agent's file reference	IMPORTANT NOTIFICATION
P3096 WO ORD	

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB 03/02473	09.06.2003	06.07.2002

Applicant
KAPITEX HEALTHCARE LIMITED et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:

European Patent Office
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Tel. +49 89 2399 - 0 Tx: 523656 epmu d

Authorized Officer

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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
P3096 WO ORD		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB 03/02473	09.06.2003	06.07.2002
International Patent Classification (IPC) or both national classification and IPC		
A61M16/04		
Applicant		
KAPITEX HEALTHCARE LIMITED et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 4 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
13.01.2004	07.07.2004

Name and mailing address of the international preliminary examining authority:	Authorized Officer
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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB 03/02473

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1, 2, 4-10	as originally filed
3	filed with telefax on 18.06.2004

Claims, Numbers

1-4, 5 (part), 10 (part), 11	received on 05.02.2004 with letter of 03.02.2004
5 (part), 6-9, 10 (part)	filed with telefax on 18.06.2004

Drawings, Figures

1A, 1B, 2, 3	as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 10 11

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 11 are so unclear that no meaningful opinion could be formed *(specify)*:

see separate sheet

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 10,11

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/ or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the Standard.

☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-9
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-9
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-9
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

III.1 Claims 10 and 11 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT, as it discloses a method for treatment of the human or animal body by surgery: a method for mounting a cannula in a tracheostomy (decision of the Board of Appeal T182/90 should be observed). Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

III.2 Furthermore claim 11 does not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. Said claim contains a reference to the drawing. According to Rule 6.2(a) PCT, claims should not contain such references except where absolutely necessary, which is not the case here.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

The document D4 was not cited in the international search report. A copy of the document is appended hereto.

D4: US-A-4 489 723 (ELLIOT SIMONS; BOULOS ROBERT) 25 December 1984 (1984-12-25)

Document **D4** is regarded as being the closest prior art to the subject-matter of claim 1, and shows s tracheostomy cannula mounting for assisting in the mounting of a cannula within a stoma of a tracheostomy patient comprising a generally planar sheet portion provided with an aperture therein of suitable size and shape to engage a channel portion of a tracheostomy cannula in interference fit so as to present a rearward mounting face adapted in use to lie against the skin of the tracheostomy patient in the vicinity of the stoma, wherein the material from which the sheet is fabricated comprises silicone rubber at least in the vicinity of the mounting face.
The subject-matter of claim 1 differs from this known device in that the material from

which the sheet is fabricated comprises a tacky silicone gel material.

The subject-matter of claim 1 is therefore new (Article 33(2) PCT).

The problem to be solved by the present invention may be regarded as how to provide a more effective, reusable air seal between a tracheal cannula and a tracheostomy.

The solution to this problem proposed in claim 1 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reasons:

- Document D4 teaches a use of Vaseline or the like lubricants to be employed between the silicone sealing member and the throat surface in order to provide a water tight seal about the tracheal stoma. Such additional substances can however irritate the skin and are more complicated in use;
- Document D1 (US-A-3 640 741) discloses a sealing ring made from a tacky gel to be used for a slow release of medications to the patient's skin around a stoma (colostomy, ileostomy). However the sealing ring of D1 comprises a material, which is not silicone and is completely soluble, therefore the ring cannot be reused. Furthermore the document teaches, that silicone is not suitable for the specific application, as it does not dissolve. D1 does not mention tacky silicone;
- An application of tacky silicone gel material for sealing purposes is not known from the prior art.

Claims 2-9 are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

V.3 Independent claim 1 should have been written in the two-part form in accordance with Rule 6.3(b) PCT, with those features known from the prior art (document D1) being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

V.4 The features of the claims should have been provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

central channel portion adapted to sit within the stoma to provide an air passage therethrough into the trachea, a forward section provided with a mounting for a stoma filter, valve or the like, and a rearward mounting section comprising an area of greater cross section, for example in the form of a resilient flange, which sits within the trachea and bears onto the tracheal surface to retain the cannula within the stoma. Such devices are fabricated of material having a degree of flexible resilience, for example medical grade silicone rubber. This assists in insertion and removal. The resilient nature of the material assists in effecting a reasonable seal between the edges of the stoma and the outer face of the central portion of the cannula, but the seal is not always perfect.

In problem patients, it has in consequence sometimes proved necessary to apply an additional seal in the form of an adhesive material between the skin around the stoma in the tracheal regions and the central portion of the cannula for example comprising medical adhesive fabric sheet or tape. Such as solution is not ideal. Any such adhesive sheet or tape would need frequent changing for hygiene purposes and the used sheet or tape would then need to be discarded. The adhesive is likely to cause irritation to sensitive skin at and around the stoma, especially in patients with a sensitive or allergic reaction to generally used adhesive materials.

It is an object of the present invention to provide a mounting for a tracheostoma cannula which provides a more effective air seal between the cannula and the stoma than is provided by conventional resilient cannula materials alone.

It is a further object of the present invention to provide a mounting for a tracheostoma cannula which mitigates some of the disadvantages of mountings based on adhesive sheet or tape.

AMENDED CLAIMS

[Received by the International Bureau on 28 November 2003 (28.11.2003); original claims 1-12 replaced by amended claims 1-1 (3 pages)]

1. A tracheostoma cannula mounting for assisting in the mounting of a cannula within a stoma of a tracheostoma patient comprising a generally planar sheet portion provided with an aperture therein of suitable size and shape to engage a channel portion of a tracheostoma cannula in interference fit so as to present a rearward mounting face adapted in use to lie against the skin of the tracheostoma patient in the vicinity of the stoma, wherein the material from which the sheet is fabricated comprises tacky silicone gel material at least in the vicinity of the mounting face.

2. A tracheostoma cannula mounting in accordance with claim 1 wherein the inner edge defining the aperture in the mounting member presents a surface of tacky gel material to contact with the cannula in use.

3. A tracheostoma cannula mounting in accordance with claim 1 or claim 2 wherein the sheet portion comprise a tacky gel layer in a multi-layer sheet.

4. A tracheostoma cannula mounting in accordance with claim 1 or claim 2 wherein the sheet portion consists essentially solely of the tacky gel material, save for an optional thin layer of non-tacky protective material at edges and/or faces of the sheet portion which are adapted to lie externally in use and/or be removed prior to use.

5. A tracheostoma cannula mounting in accordance with any preceding claim wherein the aperture in the sheet portion of the mounting member is generally circular and shaped and sized to engage the outer

circumference of the channel portion of a generally cylindrical cannula in interference fit.

6. A tracheostoma cannula mounting in accordance with claim 5 wherein the mounting member is generally circular, such that the mounting member comprises an annular portion of sheet material.

7. A tracheostoma cannula mounting in accordance with any preceding claim wherein the sheet material is 1 to 7 mm thick.

8. A tracheostoma cannula mounting in accordance with any preceding claim further comprising a removable non-tacky protective layer over the mounting surface which can readily be removed by a user to expose the tacky surface of the gel to allow the mounting member to be applied.

9. A tracheostoma cannula comprising a central channel portion adapted to be received through a stoma, a forward portion adapted to sit externally of the stoma in use and a mounting portion adapted to sit within the trachea abutting an internal surface of the stoma in use, and comprising a flange portion of increased cross section to the body portion so as to assist in retaining the cannula within the stoma, and further comprising a mounting in accordance with any preceding claim comprising a sheet portion provided with an aperture so sized and shaped as in use to be retained around the channel portion of the cannula immediately external of the stoma in interference fit, so as to present a mounting face engageable upon the external surface of the tracheal region of the wearer in the vicinity of the stoma in use.

10. A method of sealably mounting a cannula in a tracheostoma comprises the steps of inserting a cannula into the stoma, applying a mounting in

accordance with any of claims 1 to 9 therearound so as to present the mounting face to the skin of the external surface of the tracheal region of a wearer in the vicinity of the stoma, applying pressure to effect a releasable seal between mounting face and skin.

11. A tracheostoma cannula mounting, a tracheostoma cannula assembly, or a method substantially as hereinbefore described with reference to the accompanying drawings.